

REMARKS

Claims 13-15 are currently pending. In this Response, applicants amend claim 13.

Claims 13-15 are rejected under 35 U.S.C. §102(b) as being anticipated by Myers, Jr. et al. or Doroshow et al. or Myers et al. or Freeman et al., for reasons of record as they relate to claims 10-12.

This rejection is respectfully traversed.

The Examiner continues to take the position that the treatment of cancer corresponds to the treatment of cancer metastasis. However, as applicants indicated in the Response of February 4, 2000, the treatment of cancer metastasis is completely different than the treatment of cancer tumors. Normally, there is absolutely no correlation between successful treatment of cancer metastasis and successful treatment of cancer tumors with the same agent.

The Examiner indicates that Doroshow teaches that doxorubicin is an antineoplastic antibiotic that is part of a standard chemotherapeutic regimen for most hematopoietic malignancies and advanced solid tumors of the breast, ovary, thyroid and bone. This same reference also teaches the administration of N-acetyl-cysteine to protect against cardiac damage. However, applicants submit that the description indicating that doxorubicin is an anticancer agent and N-acetyl-cysteine is suitable for decreasing the side affects (i.e., cardiac toxicity) of doxorubicin does not correspond to describing or suggesting that N-acetyl cysteine is **synergistically** effective with doxorubicin in **inhibiting cancer metastasis formation**, as is disclosed in the present application.

Applicants, having found a new therapeutically valuable use for known drugs, are allowed to patent such a discovery. The use of N-acetyl-cysteine and doxorubicin in

synergistically inhibiting the formation of cancer metastasis is surely a new and valuable use which was neither disclosed nor suggested in the prior art.

On page 3 of the Office Action, the Examiner indicates that the present invention is inherently disclosed in the prior art, since the prior art discloses the use of overlapping dosage ranges for the treatment of different conditions. However, this position is inconsistent with U.S. patent law.

In order for a prior art reference to anticipate a claim through inherency, not only must the inherent property necessarily be present in the reference, **but it also must be recognized by one of ordinary skill in the art.** Public knowledge or recognition of the inherent property is required. See *Continental Can v. Monsanto*, 20 USPQ 2nd 1746 (Fed. Cir. 1991). In this case it was not until the present invention that it was recognized that the administration of doxorubicin and N-acetyl-cysteine would be synergistically useful for treating cancer metastasis (which is different and completely unrelated to the treatment of cancer tumors with doxorubicin alone). Thus, the prior art could not anticipate the present invention.

As is clearly indicated in the case law and MPEP §2112.02, the discovery of a new use for an old composition based on unknown properties of the composition is patentable to the discoverer as a new process of using the old composition. See *In re Hack*, 114 USPQ 161 (CCPA 1957). Only when the claim recites the use of an old composition and the "use" is directed to **an end result or a side effect of the composition which is concomitant with the old use**, is the claim anticipated by the prior art. *In re May*, 197 USPQ 601 (CCPA 1978). In this case, applicants have **not** found a new result or side

effect of the old composition; rather, they have found a completely different use for the composition. Because this "second medical use" is completely different than the uses of the old composition previously described in the prior art, the present invention cannot be anticipated by the prior art, based on inherency.

In the following paragraph on page 3 of the Office Action, the Examiner provides a second interpretation of "inherency". The Examiner inquires as to how applicants could determine if their patent is being infringed by another.

With all due respect to the Examiner, determining infringement is not the Examiner's concern, and is clearly is not the basis for determining **patentability** (a completely unrelated manner) by inherency. Those in the pharmaceutical industry can easily determine whether a patent is infringed if a competitor directs a patient that the combination of N-acetyl-cysteine and doxorubicin are useful for inhibiting cancer metastasis formation. As indicated in the previous sentence, however, determining infringement is not the Examiner's concern.

The Examiner further confuses the issues by indicating (in the paragraph bridging pages 3 and 4 of the Office Action) that one of ordinary skill in the art would be provided with a reasonable expectation of success that the antimalignant agent of the prior art would be useful in the treatment of cancer metastasis. This is also not the test for anticipation based on inherency; rather, this is an argument of obviousness. However, the present invention could not have been obvious in view of the prior art, since, as noted in the previous Response and above, there is no reasonable expectation of success that a compound suitable for treatment of cancer tumors would be useful in combination with N-acetyl-cysteine in the synergistic treatment of cancer metastasis. The two uses are

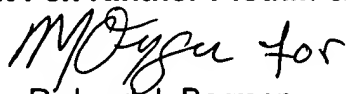
completely unrelated, as known in the prior art. In addition, the surprising synergistic results obtained with the present invention could not have been predicted from the prior art.

In order to further clarify the differences between the different invention and the prior art, applicants have amended claim 13 to indicate that the administration of N-acetyl-cysteine and doxorubicin work synergistically together to produce a cancer metastasis formation inhibiting effect. Support for the amendment can be found, for example, on page 1, lines 24-31 and page 2, line 17 through page 3, line 14.

Applicants respectfully submit that none of the prior art cited by the Examiner discloses or suggests in any way that the administration of N-acetyl-cysteine and doxorubicin work synergistically together to produce a cancer metastasis formation inhibiting effect. Applicants respectfully request that the rejection be withdrawn.

In the event this paper is not timely filed, applicants hereby petition for an appropriate extension of time. The fee for this extension may be charged to our Deposit Account No. 01-2300, along with any other additional fees which may be required with respect to this paper.

Respectfully submitted,
Arent Fox Kintner Plotkin & Kahn



Richard J. Berman
Attorney for Applicant(s)
Registration No. 39,107

1050 Connecticut Ave. N.W., Suite 600
Washington D.C. 20036-5339
Phone: 202/ 857-6000
Fax: 202/ 638-4810/4808

RJB/ccd